

Remarks/Arguments:

The pending claims are 20, 22-41, 43-49, 54-62. Claims 26, 34-38, 40, 58-62 have been withdrawn.

THE RESPONSE TO ARGUMENTS IN PARAGRAPH 2 OF THE OFFICE ACTION

Each of the points raised in paragraph 2 of the Office Action is addressed in this response.

THE GENERAL REJECTION IN PARAGRAPH 4 OF THE OFFICE ACTION

Paragraph 4 of the Office Action has rejected claims 20, 22-25, 27-33, 39, 41, 43-49 and 54-57 under 35 U.S.C. §112, first paragraph, for allegedly failing to comply with the written description requirement. Paragraph 4 of the Office Action generally contends that the claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Paragraphs 5-8 of the Office Action provide more specific reasons for the rejections.

The rejections are traversed.

**EXAMINATION REQUIREMENTS TO SUPPORT A
REJECTION UNDER 35 U.S.C. § 112, FIRST PARAGRAPH**

"An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention." MPEP § 2163, Rev. 5, Aug. 2006, p. 2100-166. "The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement." MPEP §2163.02. In addition to not requiring *in haec verba* claims, the MPEP states that newly added claim limitations may be supported in the specification through express, implicit, or inherent disclosure. MPEP § 2163, p. 2100-168. "The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed." MPEP § 2163, p. 2100-169.

"The examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims." MPEP § 2163 II.A., p. 2100-169. *Accord*, MPEP § 2163 II.A.3(b), p. 2100-177. "Prior to determining whether the disclosure satisfies the written description requirement for the

claimed subject matter, the examiner should review the claims and the entire specification, including the specific embodiments, figures, and sequence listings, to understand how applicant provides support for the various features of the claimed invention." MPEP 2163 II.A.2, p. 2100-171 (citation omitted) (emphasis added).

"In rejecting a claim, the examiner must set forth express findings of fact regarding the above analysis which support the lack of written description conclusion. These findings should:

- (A) Identify the claim limitation at issue; and
- (B) Establish a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention claimed in view of the disclosure of the application as filed."

MPEP §2163 III.A., p. 2100-178; § 2163.04 I.

THE REJECTION IN PARAGRAPH 5 OF THE OFFICE ACTION

Paragraph 5 of the Office Action has rejected claims 20, 22-25, 27-33, 39, 41, 43-49, and 54-57 because independent claims 54 and 56 each recites vertices that abut and, in the PTO's view, abutting apices are not disclosed in the specification. Instead, the PTO contends that the specification only discloses juxtaposed vertices. Applicants disagree.

Claim 54 recites, in part, "means for securing an apex of one hoop to an abutting juxtaposed apex of a neighboring hoop." Claim 56 recites, in part, "at least some of said vertices axially abut." Even though Applicants' specification does not expressly use the term "abut," a person skilled in the art would recognize that the specification (including the figures) expressly, implicitly, and inherently supports these claim limitations. The PTO has not established a *prima facie* case, with reasons, explaining why a person skilled in the art would not have recognized that Applicants' disclosure shows they were in possession of the claimed invention.

The specification states, in part

Typically, the stents of this invention whether of the helical or perpendicular variety, also comprise a securing means for securing an apex of the sinuous wire in one hoop to a juxtaposed apex of a neighboring hoop so that each hoop is supported by its neighbors. The securing means may comprise a loop element of a suture material, for example, to tie the juxtaposed apices together.
... (page 10, lines 16-23)

This passage states that an apex of one hoop is secured to a juxtaposed apex of a neighboring hoop "so that each hoop is supported by its neighbors." It also states that "a suture material. . .tie[s] juxtaposed apices together." One skilled in the art would recognize that the specification at least implicitly and inherently describes an embodiment including abutting apices, thereby supporting the claim language at least implicitly and inherently. The PTO has not provided any evidence or reasons demonstrating that a person skilled in the art at the time the application was filed would not have recognized that the inventors were in possession of the claimed invention in view of the above passages in the disclosure.

One skilled in the art would also recognize that the above passages describe the stent embodiment selected for illustration in Figs. 1A, 1B, 2A, 4A, and 4B-4F. (page 19, lines 11-12, 20-21). These figures clearly show an embodiment in which juxtaposed apices of neighboring hoops abut. The PTO has not explained why a person skilled in the art would not recognize that the figures show abutting apices.

As stated above, the subject matter of a claim need not be described *in haec verba*. Consideration of the specification and the figures, undertaken from the standpoint of one of skill in the art, "conveys with reasonable clarity" that Applicants were in possession of the claimed invention. MPEP § 2163, p. 2100-169.

In contrast, the PTO has not presented evidence or reasons why a person skilled in the art would not recognize that the written description of the invention, including the figures and passages specifically identified above, supports the claims. Instead, paragraph 5 of the Office Action states only: "[t]he specification only disclose juxtaposed vertices." This single statement fails to evidence that a person skilled in the art would not recognize that the Applicants had possession of the claimed invention. It fails to recognize the embodiments described by the specification and the figures.

For all of the above reasons, Applicants request the PTO to withdraw the rejections of claims 54 and 56 stated in paragraph 5 of the Office Action.

THE REJECTION IN PARAGRAPH 6 OF THE OFFICE ACTION

Paragraph 6 of the Office Action has rejected claims 20, 22-25, 27-33, 39, 41, 43-49 and 54-55. Claim 54 recites, in part,

a plurality of hoops aligned along a common axis, each of said hoops being non-helical and oriented in a plane substantially perpendicular to the longitudinal axis of the stent.

The PTO has made the rejection "because independent claim 54 recites 'non-helical' in combination with each hoop being substantially perpendicular and having connected apices." In the PTO's view, "[t]he specification only disclose embodiments wherein each hoop is substantially perpendicular and has connected apices and has a helical 'offset' feature." Applicants disagree.

Applicants' specification expressly describes two alternative categories of embodiments of hoops, helical and substantially perpendicular. The specification states:

In some embodiments the wire may have a helical configuration as disclosed in EP-A-0556850. Alternatively, the wire may be of an entirely novel configuration, namely one in which the wire forms a plurality of hoops such that the plane of the circumference of each hoop is substantially perpendicular to the longitudinal axis of the stent. (page 9, lines 13-19)

One of ordinary skill in the art would recognize that the specification conveys with reasonable clarity a plurality of embodiments and features. One described embodiment is a helical configuration. One of ordinary skill in the art would recognize that the alternative to the helical embodiment described in the specification is not helical because the specification describes an alternative to a helical embodiment. That is, one of ordinary skill in the art would recognize that at least one alternatively described embodiment is non-helical.

This portion of the specification also makes clear that embodiments of Applicants' invention may be helical or perpendicular: "[t]ypically, the stents of this invention [are] of the helical or perpendicular variety." (page 10, lines 16-17). The phrase "helical or perpendicular variety" confirms that the "perpendicular variety" embodiment is an explicitly disclosed example of a non-helical alternative to the helical variety.

As indicated above, paragraph 6 of the Office Action contends that the application does not disclose "'non-helical' in combination with each hoop being substantially perpendicular and having connected apices." To the contrary, the specification does disclose such an embodiment (although not *in haec verba*) by stating:

Typically, the stents of this invention . . . of the . . . perpendicular variety, also comprise a securing means for securing an apex of the sinuous wire in one hoop to a juxtaposed apex of a neighboring hoop so that each hoop is supported by its neighbors. (page 10, lines 16-20)

One of ordinary skill in the art would recognize that this paragraph also provides support for the claimed combination.

For all of the above reasons, Applicants' disclosure demonstrates that they had possession of this aspect of the claimed invention and Applicants therefore request the PTO to withdraw the rejection stated in paragraph 6 of the Office Action.

THE REJECTION IN PARAGRAPH 7 OF THE OFFICE ACTION

Claim 56 recites, in part

vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member.

Paragraph 7 of the Office Action has rejected claims 56 and 57 because, in the view of the PTO, the specification does not provide support for the recitation that vertices of "each hoop" lie in a common plane perpendicular to the longitudinal axis of the tubular member. In the view of the PTO, the specification only supports a recitation that apices of "one or more" hoops lie in such a plane. The Office Action also contends that only a recitation of "substantially perpendicular" is supported by the description of Figs. 1-4. Applicants disagree.

The specification contains broad language generally describing selected embodiments of its disclosed stents as being of a "perpendicular variety." (page 10, line 17) The specification also discloses that its stents of the "perpendicular variety" "comprise a securing means for securing an apex of the sinuous wire in one hoop to a juxtaposed apex of a neighboring hoop so that each hoop is supported by its neighbors." (page 10, lines 16-19). One exemplary embodiment may have hoops that are "substantially perpendicular to the longitudinal axis" (page 23, lines 21-22, discussing Fig. 2A). Other exemplary embodiments of the perpendicular variety are straight stents (page 44, lines 19-20) having hoops that are "perpendicular to a common axis." (page 44, lines 22-23, discussing Figs. 22 and 23).

Figs. 1A and 2A, among other figures, illustrate an embodiment of a stent 10 (page 22, lines 17-18) having hoops 20. (page 23, line 11-page 24, line 13). These figures illustrate a stent embodiment that is an embodiment of the "perpendicular variety" having "juxtaposed apices 22 of neighboring hoops 20 are secured together. . . Each apex 22 of each hoop 20 which has a juxtaposed apex of a neighboring hoop 20 is tied to the juxtaposed apex 22." (page 25, lines 4-9). See also, page 23, lines 20-23 ("Each hoop 20 is wound onto mandrel 46 such that the plane of the circumference of each hoop 20 is substantially perpendicular to the longitudinal axis of the mandrel 46.")

Fig. 22 illustrates another embodiment of a stent using the stent configurations described in Figs. 1A and 2A. Fig. 22 illustrates, for example, a stent embodiment having a

proximal portion 401 "formed of a number of longitudinally spaced hoops 20 as described in connection with the formation of stent 10 above." (page 45, lines 5-7). The stent embodiment illustrated in Fig. 22 also has a distal portion 402 having additional similar hoops 20. (page 45, lines 10-12). This embodiment is also a stent of the "perpendicular variety." (page 44, lines 21-23) ("each of the requests comprising one or more adjacent hoops, perpendicular to a common axis").

Since the stent embodiment shown in Figs. 1A, 2A and stent embodiments shown in Figs. 22, 23 are both of the "perpendicular variety," and since both stents may be formed in the same way, one skilled in the art would understand that either of the stents could be formed of substantially perpendicular hoops or could be formed of perpendicular hoops.

In addition, Fig. 1A, illustrating stent embodiment 10, clearly shows "vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member." As indicated by the MPEP, the PTO must consider Applicants' figures when construing their full disclosure. The specification cannot be considered in a vacuum, without giving full weight to the clear teachings of the figures.

For the above reasons, Applicants' disclosure supports the phrase "the vertices of each hoop pointed in the axial direction lie in a common plane perpendicular to the longitudinal axis of the tubular member." Applicants therefore request the PTO to withdraw the rejection stated in paragraph 7 of the Office Action.

THE COMMENTS REGARDING THE ORIGINALLY FILED
ABSTRACT IN PARAGRAPH 8 OF THE OFFICE ACTION

In their Amendment filed on August 6, 2007, Applicants inadvertently relied upon the Abstract as originally filed. The Office Action has correctly pointed out that Applicants substituted a new Abstract for the originally filed Abstract in a Preliminary Amendment filed on March 1, 2002. Even though the original Abstract has been canceled, paragraph 8 of the Office Action states that the originally filed Abstract "appear[s] to contain new matter as compared to the parent application, 08/312,881" because, it contends, the specification "fail[s] to support the combination (perpendicular and connected abutting apices)." Applicants disagree. As explained above, these features are shown in Applicants' disclosure, which includes the specification and figures specifically cited above.

New matter is "[m]atter not in the original specification, claims, or drawings." MPEP §608.04(a). The existence of new matter is not determined by comparing only isolated parts of the disclosure. Accordingly, a determination of whether a new Abstract contains new

matter cannot be made only by comparing the new Abstract with the original Abstract. Instead, a new Abstract must be compared with the entire original disclosure comprising the specification, figures, and claims. The Office Action's determination of purported new matter is based solely upon a comparison of the originally filed Abstract with the Abstract filed in priority Application No. 312,881. Such a comparison is insufficient for purposes of determining the existence of new matter.

MPEP § 608.04 states that "[w]hen new matter is introduced into the specification, the amendment should be objected to under 35 U.S.C. 132 . . . and a requirement made to cancel the new matter." See also, MPEP § 2163.06 I., p. 2100-184. The Office Action did not object to the originally filed Abstract under § 132 and did not require Applicants to cancel it.

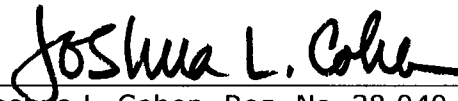
Accordingly, no response to paragraph 8 is required. Nevertheless, Applicants respectfully request the PTO to withdraw its incorrect suggestion that the originally filed Abstract contained new matter.

CONCLUSION

Applicants thank the Examiner for indicating inferentially that none of the pending claims are rejected over any prior art.

Since all of the pending claims have support in the specification, all of the pending claims are now in condition for allowance and Applicants request an early indication of allowance.

Respectfully submitted,



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